IRON DEXTRAN COMPLEX
CAS No. 9004-66-4
First Listed in the *Second Annual Report on Carcinogens*

CARCINOGENICITY

Iron dextran complex is *reasonably anticipated to be a human carcinogen* based on sufficient evidence of carcinogenicity in experimental animals (IARC V.2, 1973; IARC S.4, 1982). When administered by subcutaneous injection iron dextran complex induced local sarcomas in mice and hamsters of both sexes and male rats. When administered by intramuscular injection, iron dextran complex induced local sarcomas in rats and rabbits of both sexes.

There is inadequate evidence for thecarcinogenicity of iron dextran complex in humans (IARC S.7, 1987). There have been case reports of cancers associated with injections of iron dextran in human subjects. Tumors appeared at the probable sites of injection, and the similarity of the local effect in humans and animals was noted by an IARC Working Group.

PROPERTIES

Iron dextran is a complex of ferric hydroxide with dextran, a polysaccharide. Iron dextran complex is very soluble in water and DMSO. Iron dextran decomposes in 95% ethanol and acetone. A typical product contains 5% weight/volume iron and 20% weight/volume dextran. Iron dextran is combustible. The product for human use is a sterile, dark brown, colloidal solution in saline; the products designed for use in animals are more concentrated.

USE

Iron dextran complex is used for parenteral treatment of iron-deficiency anemia in humans and baby pigs and as a hematinic (IARC V.2, 1973 and Radian, 1991).

PRODUCTION

Iron dextran complex is currently produced domestically by one manufacturer, but there is no record of the amount produced (SRIc, 1986). No data on imports or exports were available. In 1980, pharmacists dispensed 30,000 prescriptions for iron dextran. Iron dextran complex was introduced in the United States in 1957 (IARC V.2, 1973).

EXPOSURE

The primary routes of potential human exposure to iron dextran complex are deep intramuscular injection, inhalation, and dermal contact. The therapeutic dose of iron dextran for humans is 1-5 ml (50-250 mg of iron) daily (IARC V.2, 1973). Use is advised solely for those patients who do not respond to oral administration of iron. Clear warning of potential injection site sarcoma is included with the physician's package insert. The National Occupational Exposure Survey (1981-1983) estimated that 1,157 total workers, including 573 women, potentially were exposed to iron dextran complex in the workplace (NIOSH, 1984). Potential

occupational exposure to iron dextran complex may occur during the production, formulation, packaging, or administration of the pharmaceuticals. Exposure during production may be site-limited because the compound is produced by a single manufacturer.

REGULATIONS

EPA regulates iron dextran complex under the Resource Conservation and Recovery Act (RCRA) and the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA). A reportable quantity (RQ) of 5,000 lb was proposed for iron dextran complex under CERCLA. It is regulated as a hazardous constituent of waste under RCRA. EPA proposed to remove iron dextran from CERCLA and RCRA designations, based on an EPA conclusion that disposal of this substance does not pose a hazard. Iron dextran complex is not included in the list of hazardous substances and reportable quantities (8/14/89). FDA regulates iron dextran complex under the Food, Drug, and Cosmetic Act (FD&CA) as an animal drug. OSHA regulates iron dextran complex under the Hazard Communication Standard and as a chemical hazard in laboratories. Regulations are summarized in Volume II, Table B-74.